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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/728,421	11/28/2000	Steven K. Yoshinaga	A-579D	4100
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AMGEN INC.				
MAIL STOP 28-2-C				
ONE AMGEN CENTER DRIVE				
THOUSAND OAKS, CA 91320-1799				
EXAMINER				
GAMBEL, PHILLIP				
ART UNIT		PAPER NUMBER		
1644				
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01/20/2011		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary****Application No.**

09/728,421

**Applicant(s)**

YOSHINAGA, STEVEN K.

**Examiner**

Phillip Gambel

**Art Unit**

1644

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 February 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 39-58 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 43 and 46-48 is/are allowed.
- 6) ☒ Claim(s) 39-42, 44, 45, 49-58 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date 11/16/2007

### DETAILED ACTION

1. The decision on the Petition, filed 02/11/2005, under 37 CFR 1.137(b), to revive the instant application was granted and mailed on 03/02/2005.

This Office Action should serve in response to applicant's Status Letter, filed 10/26/2007.

2. Applicant's amendment, filed 02/11/2005, has been entered.

Claims 39-41, 44, 46-47 and 49-51 have been amended.

Claims 1-38 have been canceled previously.

Claims 39-58 as they relate to nucleic acids encoding a B7RP1 polypeptide (SEQ ID NOS: 6, 11 and 16) are under consideration in the instant application.

3. The text of those sections of Title 35 USC not included in this Action can be found in a prior Office Action.

This Action will be in response to applicant's arguments, filed 02/11/2005.

The rejections of record can be found in the previous Office Action, mailed 06/03/2004.

4. If applicant desires priority under 35 U.S.C. 120 based upon a previously filed copending application, specific reference to the earlier filed application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. \_\_\_\_\_" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

Again, applicant should amend the first sentence of the instant specification to update the status of the priority documents.

5. Upon reconsideration of applicant's amended claims, filed 02/11/2005, the previous rejections under 35 U.S.C. 112, second paragraph, have been withdrawn.

6. Claims 39, 41, 45, 49-52 and 54-58 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. The specification as originally filed does not provide support for the invention as now claimed:

(a) “a nucleotide sequence of (b) encoding a polypeptide of at least about 100 amino acid residues of SEQ ID NO: 7, wherein the polypeptide fragment has at least one activity selected from a T cell proliferation activity, a T cell activation activity and a binding activity to CRP1” (see claim 39);

(b) “a nucleotide sequence encoding a polypeptides as set forth in Figure 12A (SEQ ID NO: 17) from about residues 19-302, 20-302, 21-302, 22-302, 24-302 or 28-302, wherein the polypeptide has at least one activity selected from a T cell proliferation activity, a T cell activation activity and a binding activity to CRP1” (see claims 41 and 45);

(c) “comprising a carboxy terminus at residue 302” (see claim 47);

(d) “at least about 50 amino acid residues, wherein the fragment comprises an amino acid sequence that is at least about 95% identical to an amino acid sequence as set forth in Figure 12A (SEQ ID NO: 17) and has at least one activity selected from a T cell proliferation activity, a T cell activation activity and a binding activity to CRP1” and wherein the nucleotide sequence is not the nucleotide sequence of GenBank Accession No. AB014533 or GenBank Accession No. R23544” (see claim 51); and

(e) “Accession No. R23544” (see claims 49-51).

Applicant's amendment, filed 02/11/2005, asserts that no new matter has been added and directs support to certain sections of the instant disclosure as indicated herein.

b) the nucleotide sequence encoding the polypeptide as set forth in Figure 2A (SEQ ID NO: 6) from residues 1-322 or from residues 47-322 or as set forth in Figure 3A (SEQ ID NO: 11) from residues 1-288 or from residues 19-288, 20-288, 21-288, 22-288, 24-288, or 28-288; or as set forth in Figure 12A (SEQ ID NO: 16) from residues 1-302 or from residues 19-302, 20-302, 21-302, 22-302, 24-302 or 28-302;  
See amendment, filed 05/05/2003 for page 5 of the specification.

c) a nucleotide sequence encoding a polypeptide that is at least about 70 percent identical to the polypeptide as set forth in Figure 2A (SEQ ID NO: 6) or Figure 3A (SEQ ID NO: ii) or Figure 12A (SEQ ID NO: 16)  
See page 5, lines 12-16 of the original specification.

f) a nucleotide sequence of (b), (c) or (d) encoding a polypeptide fragment of at least about 25, 50, 75, 100, or greater than 100 amino acid residues;  
See page 5, lines 21-23 of the original specification upon which applicant relies upon.

Polypeptides that are at least about 70 percent identical will typically have one or more amino acid substitutions, deletions, and/or additions as compared to a wild type CRPI or B7RPI polypeptide. In preferred embodiment, polypeptides will have about 75%, 80%, 85%, 90% or 95% identity to CRPI or B7RPI polypeptides.

See page 46, lines 11-14 of the original specification upon which applicant relies upon.

However, the instant specification as filed does not provide sufficient written description for: “at least about 100 amino acid residues of SEQ ID NO: 7”;

“residues 19-302, 20-302, 21-302, 22-302, 24-302 or 28-302” in the context of SEQ ID NO: 17;

“comprising a carboxy terminus at residue 302”;

“at least about 50 amino acid residues ... at least about 95% identical to an amino acid sequence as set forth in Figure 12A (SEQ ID NO: 17); or

“Accession No. R23544”.

In contrast to applicant's assertions, page 5, lines 21-23 of the specification does not describe SEQ ID NO: 7.

In contrast to applicant assertions, page 5, lines 10-11 of the specification does not describe the residues in the context of SEQ ID NO: 17.

In contrast to applicant's assertions, page 5, lines 10-11 of the specification does not describe “comprising a carboxy terminus at residue 302”.

In contrast to applicant's assertions, pages 5 and 46 of the specification do not describe “at least about 100 amino acid residues of SEQ ID NO: 7”.

In contrast to applicant's reliance upon In re Johnson and Farnham, 194 USPQ 187 (CCPA 1977),

applicant does not provide sufficient written description in the application as filed for “Accession No. R23544” and cannot disclaim material which is insufficiently supported by the written description of the application as filed.

There is a lack of sufficient specificity and particularity to GenBank R23544 in the application as filed.

The specification does not provide sufficient blazemarks nor direction for the instant claims encompassing the above-mentioned “limitations”, as currently recited and addressed herein. The instant claims now recite limitations which were not clearly disclosed in the specification as-filed, and now change the scope of the instant disclosure as-filed. Such limitations recited in the present claims, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

Applicant is required to cancel the new matter in the response to this Office Action.

Alternatively, applicant is invited to provide sufficient written support for the “limitations” indicated above. See MPEP 714.02 and 2163.06

7. GenBank Accession No. AB014533:

Claims 40, 42, 44 and 49-51, 53 and 55-58 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention

Applicant's request, filed 02/11/2005, that any amendment of the specification to include the nucleotide sequence of GenBank Accession No. ABO14533 should such an amendment be necessary, be held in abeyance pending resolution of the other outstanding rejections.

This rejection under 35 U.S.C. 112, first paragraph is maintained for the reasons of record.

The following is reiterated for applicant's convenience.

The nucleotide sequence of GenBank Accession No. AB014533 is required to practice the claimed invention. As a required element, it is essential that the nucleotide sequence of GenBank Accession No. AB014533 be supported by the instant application.

The current Sequence Listing does not appear to provide for nucleotide sequence of GenBank Accession No. AB014533.

Applicant is reminded to provide said Sequence Listing which complies with the requirements of 37 CFR 1.821 through 1.825 for Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Applicant is reminded to provide the appropriate Hawkins Declaration to accompany amending the instant specification to provide the essential subject defining the claimed nucleotide sequence of GenBank Accession No. AB014533.

Applicant is reminded that to incorporate material by reference, the host document must identify with detailed particularity what specific material it incorporates and clearly indicate where the material is found in the various documents. See Advanced Display Systems, Inc. v. Kent State Univ., 54 USPQ2d 1673 (Fed. Cir. 2000) citing In re Seversky, 177 USPQ 144, 146 (CCPA 1973).

Applicant is required to provide evidence that the nucleotide sequence of GenBank Accession No. AB014533 that is to be incorporated by reference into the instant application is the same nucleotide sequence that was indicated at the time of filing of the earliest priority document relied upon (e.g. USSN 09/244,448) and indicate where the nucleotide sequence of GenBank Accession No. AB014533 is supported by said priority document.

The following is noted.

The incorporation of essential material in the specification by reference to a foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. See In re Hawkins, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); In re Hawkins, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); and In re Hawkins, 486 F.2d 577, 179 USPQ 167 (CCPA 1973).

An application as filed must be complete in itself in order to comply with 35 U.S.C. 112; however this does not bar incorporation by reference. Ex parte Schwarze, 151 USPQ 426 (Bd. of Appeals, 1966). an application for a patent when filed may incorporate "essential material" by reference to (1) a United States patent or (2) an allowed U.S. application, subject to the conditions set forth below. "Essential material" is defined as that which is necessary to (1) support the claims, or (2) for adequate disclosure of the invention (35 U.S.C. 112). "Essential material" may not be incorporated by reference to (1) patents or applications published by foreign countries or regional patent offices, to (2) non-patent publications, to (3) a U.S. patent or application which itself incorporates "essential material" by reference or to (4) a foreign application. See In re Fouché, 169 USPQ 429; 439 F.2d 1237 (CCPA 1971).

Nonessential subject matter may be incorporated by reference to (1) patents or application published by the United States or foreign countries or regional patent offices, (2) prior filed, commonly owned U.S. applications or (3) non-patent publications, for purposes of indicating the background of the invention or illustrating the state of the art.

The referencing application must include (1) an abstract, (2) a brief summary of the invention, (3) an identification of the referenced patent or application, (4) at least one view in the drawing in those applications admitting of a drawing, and (5) one or more claims. Particular attention should be directed to specific portions of the referenced patent or application.

Applicant is reminded that the amendment must point to a basis in the specification so as not to add any new matter. See MPEP 714.02 and 2163.06

GenBank R23544: It has been noted that the nucleotide sequence of GenBank R23544 would be subject to the same incorporation by reference as essential subject matter to satisfy the enablement requirements under 35 USC 112, first paragraph.

However, given the absence of any written support for GenBank R23544 in the application as filed, the recitation of GenBank 23544 is subject to the new matter rejection under 35 USC 112, first paragraph, indicated above.

8. Upon reconsideration of applicant's amended claims, filed 02/11/2005, the previous rejections under 35 U.S.C. 112, first paragraph, written description, with respect to the recitation of "CRP1" and "B7RP1" have been withdrawn.

9. Upon reconsideration of applicant's amended claims, filed 02/11/2005, the previous rejections under 35 U.S.C. 112, first paragraph, enablement with respect to the recitation of "CRP1" and "B7-RP1" have been withdrawn.

10. Upon reconsideration of applicant's amended claims and arguments, filed 02/11/2005, the previous prior art rejections under 35 U.S.C. 102(a), 102(b) and 103(a) have been withdrawn.

11. Upon reconsideration of the abandonment of USSN 09/728,420, the previous provisional rejection under the judicially created doctrine of obviousness-type double patenting has been withdrawn.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Phillip Gambel/  
Primary Examiner  
Technology Center 1600  
Art Unit 1644  
January 18, 2011